PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61N 1/36	A1	(11) International Publication Number:	WO 97/26042
		(43) International Publication Date:	24 July 1997 (24.07.97)

(21) International Application Number: PCT/RU96/00311

(22) International Filing Date: 31 October 1996 (31.10.96)

(30) Priority Data:
96100043 18 January 1996 (18.01.96) RU

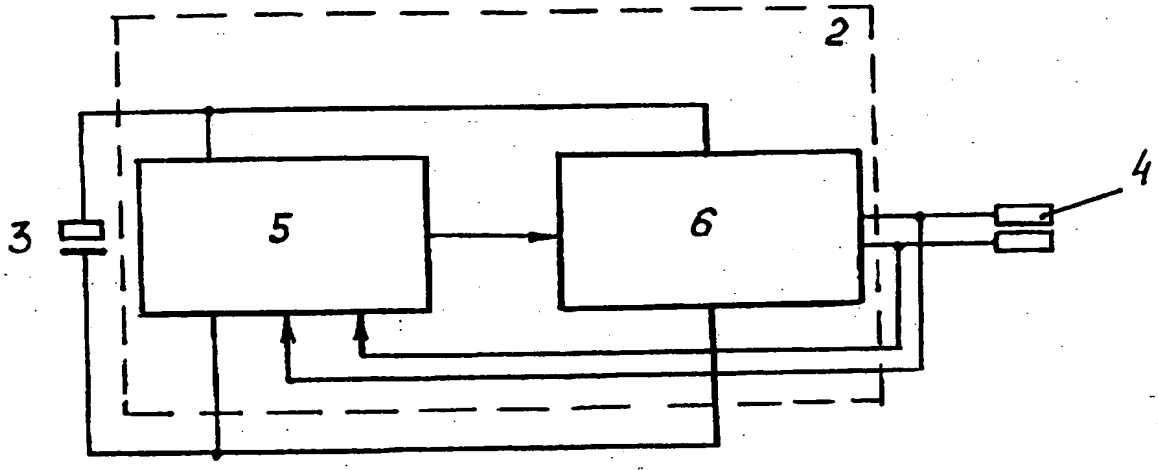
(71) Applicant *(for all designated States except US)*: OPEN JOINT-STOCK COMPANY "PLANT "KOMPONENT" [RU/RU]; Plant Komponent Ltd., Zelenograd, Moscow, 103460 (RU).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: TEREKHIN, Jury Vladimirovich [RU/RU]; Zelenograd 116-36, Moscow, 103480 (RU). OUGADTCHIKOV, Anatoli Leontievich [RU/RU]; Zelenograd 1110-20, Moscow, 103460 (RU).

(81) Designated States: AU, CN, CZ, JP, US, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

(54) Title: ELECTRICAL STIMULANT FOR ALIMENTARY TRACT



(57) Abstract

The invention relates to the medical equipment and can be used, for example, in post-surgical therapy in outpatient clinics and in hospitals, as well as prophylactic measure at alimentary tract diseases. Essence: an electrical stimulant contains capsule (1), in which consecutively connected unit (5) for testing parameters of external medium and pulses driver (6), connected to power supply (3), are located. Electrodes (4) are provided on the external surface of capsule (1), total in number (2 + n), where n = 0, 1, 2, ..., and is defined by a degree of healing effect for some or other disease and technological possibility of the electrodes manufacture. Electrodes (4) are connected with the output of pulses driver (6) and also with inputs of unit (5). In case of multi-electrodes form of the electrical stimulant two electrodes only are connected both with the unit (6) and the unit (5).

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	**GB**	United Kingdom	**MW**	Malawi
AT	Austria	**GE**	Georgia	**MX**	Mexico
AU	Australia	**GN**	Guinea	**NE**	Niger
BB	Barbados	**GR**	Greece	**NL**	Netherlands
BE	Belgium	**HU**	Hungary	**NO**	Norway
BF	Burkina Faso	**IE**	Ireland	**NZ**	New Zealand
BG	Bulgaria	**IT**	Italy	**PL**	Poland
BJ	Benin	**JP**	Japan	**PT**	Portugal
BR	Brazil	**KE**	Kenya	**RO**	Romania
BY	Belarus	**KG**	Kyrgystan	**RU**	Russian Federation
CA	Canada	**KP**	Democratic People's Republic of Korea	**SD**	Sudan
CF	Central African Republic			**SE**	Sweden
CG	Congo	**KR**	Republic of Korea	**SG**	Singapore
CH	Switzerland	**KZ**	Kazakhstan	**SI**	Slovenia
CI	Côte d'Ivoire	**LI**	Liechtenstein	**SK**	Slovakia
CM	Cameroon	**LK**	Sri Lanka	**SN**	Senegal
CN	China	**LR**	Liberia	**SZ**	Swaziland
CS	Czechoslovakia	**LT**	Lithuania	**TD**	Chad
CZ	Czech Republic	**LU**	Luxembourg	**TG**	Togo
DE	Germany	**LV**	Latvia	**TJ**	Tajikistan
DK	Denmark	**MC**	Monaco	**TT**	Trinidad and Tobago
EE	Estonia	**MD**	Republic of Moldova	**UA**	Ukraine
ES	Spain	**MG**	Madagascar	**UG**	Uganda
FI	Finland	**ML**	Mali	**US**	United States of America
FR	France	**MN**	Mongolia	**UZ**	Uzbekistan
GA	Gabon	**MR**	Mauritania	**VN**	Viet Nam

ELECTRICAL STIMULANT FOR ALIMENTARY TRACT

Technical field

This invention relates to the medicine and medical equipment and can be used in a post-surgical period for rehabilitation of sick people suffered from weak functioning of internal organs, located close to the alimentary tract, as well of all parts of alimentary tract, by a method of "soft therapy" by means of per oral consumption of the electrical stimulant. The invention can be recommended also as prophylactic measure at various kinds of alimentary tract diseases, for use in hospitals and outpatient clinics as well as by patients themselves according to the recommendation of a doctor.

Background Art

There is a problem at present all over the world of treatment and restoration of weakened various parts of the alimentary tract, and also of internal organs, functionally connected with the alimentary tract.

The use of a "soft therapy" by means of electrical stimulation at a qualitatively new level is one of the ways for solving this problem.

An electrical stimulant for the alimentary tract is known, which contains drainage tubes with electrodes located on them (inventor's certificate SU 1389776, IPC A 61 M 25/00, A 61 B 5/04, of April 23, 1988).

This electrical stimulant can be used in hospitals only and by specially trained staff; there are some probability of patients injuries at the introduction and removal of the device with all additives, including electrodes, through the

nasopharynx. Its efficiency may be insufficient because of narrow framework of its action.

An electrical stimulant of the alimentary tract, which is described in inventor's certificate SU 936931, IPC A 61 N 1/36 of June 23, 1982, may be considered as the nearest to the claimed invention according to the entirety of their essential features. That electrical stimulant contains a capsule with a power supply and a generator of pulses located inside. A capsule case is executed in a form of two electrically isolated parts, serving as electrodes being in the contact with the intestine walls after the capsule was swallowed.

The electrical stimulant works as follows.

The series of rectangular pulses of predetermined parameters arrive from the generator to the electrodes, which contact the intestine walls, influence them and cause response in the form of a peristalsis wave, which transports the electrical stimulant and contents of intestines to distal parts, where the process is repeated until the capsule will leave the alimentary tract by a natural way through the anus.

However the known electrical stimulant has relatively low efficiency of electrical stimulation, because the electrical field of two electrodes corresponds to morphology of muscular fabric of the alimentary tract only partially, and because there is no adaptation of the stimulation to conditions of various parts of the alimentary tract. Besides, it is characterized by inefficient power consumption that can affect operational reliability. Besides, absence of the stimulation adaptation to conditions of various parts of the alimentary tract can result in collateral actions on patient's body.

Insufficient efficiency of the electrical stimulation, caused by absence of stimulation adaptation to conditions existing in various parts of the alimentary tract is explained by that each part of the alimentary tract which is passed by the electrical stimulant has its own peculiarities:

- morphological features (geometrical size, direction and etc.);

- its own particular value of content's pH factor, which determines a functional and physiological purpose of the given part.

The known electrical stimulant produces electrical pulses with mean parameters, which are not optimized for each part of the tract.

The relatively low efficiency of electrical stimulation caused by a partial adjustment of the electrical field of two electrodes with the morphology of the muscular tissue of the alimentary tract, is explained by the following. The muscular tissue contains an external longitudinal and internal circular layers. The electrical effect on those layers requires availability of electrical fields having changing parameters and/or mutually orthogonal strength directions, which are not available by use of the known electrical stimulant. At the movement of the known electrical stimulant, the electrical field of two electrodes stimulates basically the longitudinal muscular layer only, i.e. the peristalsis wave does not arise in this case or arises rarely and has unstable character, that reduces the efficiency of the electrical stimulation.

The low reliability of the known electrical stimulant as the result of inefficient energy consumption is explained by impossibility of minimization of energy consumption in the mode of passive storage, because the known electrical stimulant has been in the condition of dynamic mode of operations constantly, since the moment of its manufacturing, and further during storage, and after the introduction in the patient's alimentary tract.

Disclosure of Invention

The invention is directed to solving the following problems:

- designing an electrical stimulant, which is provided for electrical fields having changing parameters and also electrical fields which strength direction is mutually orthogonal.

- minimization the energy consumption in a mode of storage and consequently improving the reliability.

The essence of the claimed invention consists in that the electrical stimulant of the alimentary tract contains a capsule with two electrodes, which are provided on the outer surface of the capsule, and the power supply located inside, wherein a unit for testing parameters of external medium and a pulses driver, which are consecutively connected, are additionally located in the capsule, and n electrodes, where n = 0, 1, 2, ..., and it is defined by a degree of healing effect for some or other disease and technological possibility of the electrodes manufacture, are provided on the external surface of the capsule, the electrodes being connected with outputs of the pulses driver and two electrodes being connected also with inputs of the unit for testing parameters of external medium.

Besides the capsule can be made in the form of a tubular element with covers, each opposite end of the tubular element being provided by electrodes located on the cylinder surface.

Besides the capsule can be made in the form of two interconnected caps, each being provided by electrodes located on the generatrix surface.

So it is clear from the technical essence of the invention that the electrical stimulant may be drafted in bi-electrodes form as well as in multi-electrodes one.

What about the newly introduced units, the additional use of the unit for testing parameters of external medium connected with the pulses driver and the electrodes provides for a feedback in the power supply circuit of the electrical stimulant.

The unit for testing parameters of external medium registers the resistance between the electrodes which is near to infinity in the mode of electrical stimulant storage and the output signal of the unit blocks the clock frequency which is responsible for the operation mode of the pulses driver. So, the electrical stimulant is in the non-working position with minimum energy consumption. When the electrical stimulant enters into the alimentary tract, anus or vagina, the resistance is lowering down to the level of several kilo ohms (kOm) and the units' for testing parameters of external medium output signal coming to the managing (control) input of the pulses driver permits to start on the pulses driver and to pass it on to the working mode of electrical stimulation.

The pulses driver provides for series of pulses with required parameters depending on external medium pH factor.

A microprocessor which have stored in memory the necessary number of groups of stimulating parameters can be used as the pulses driver.

Two electrodes are used not only for electrical stimulation but also - in a pause between series of pulses - for measurement of the resistance between them, in bi-electrodes as well as in multi-electrodes form of the electrical stimulant.

In the electrical stimulant bi-electrodes form the pulses driver signals on the electrodes provide for bi-phase, orthogonal change of the electrical field vector. Parameters of the stimulating pulses can change during the electrical stimulant transportation through the alimentary tract depending on the external medium pH factor.

In the electrical stimulant multi-electrodes form the pulses driver signals on the electrodes provide for multi-phase electrical field with discreteness of n!, where n is the number of the electrodes. In this case parameters of the stimulating pulses can also change during the electrical stimulant transportation through the alimentary tract.

Brief Description of Drawings

The essence of the invention is explained by the drawings, where:

Fig.1 shows a functional electrical diagram of the electrical stimulant in bi-electrodes form.

Fig.2 represents a constructive embodiment of the electrical stimulant with the capsule designed in the form of a tubular element with covers, each opposite end of the tubular element being provided by one electrode located on the cylinder line (bi-electrodes form).

Fig.3 is a constructive embodiment of the electrical stimulant with the capsule designed in the form of two interconnected caps, each being provided by the electrodes located on the generatrix line of the cap (multi-electrodes form).

Fig.4 shows an electrical diagram of the unit for testing parameters of external medium, example for bi-electrodes form of the electrical stimulant.

Fig.5 is an electrical diagram of the pulses driver, example for multi-electrodes form of the electrical stimulant.

Electrical diagrams of fig.4 and fig.5 are the examples of possible embodiments of these blocks and, as well as the illustrating text in the description relating to them, in no means may limit claims of the applicant. The applicant may be free to use another embodiment of the units represented in fig 4 and fig 5.

Best Mode for Carrying Out the Invention

The proposed alimentary tract electrical stimulant contains capsule 1, in which an electronic block 2 and power supply 3 are located. Electrodes 4 are provided on the external surface of capsule 1, the total number of the electrodes equals (2 + n), where n = 0, 1, 2, ... The

electronic block 2 consists of the consecutively connected unit 5 for testing parameters of external medium and pulses driver 6.

The electrodes 4 in the bi-electrodes form are connected with outputs of the pulses driver 6 and with inputs of the unit 5 for testing parameters of external medium, and in multi-electrodes form, two electrodes 4 only are connected with inputs of the unit 5.

Capsule 1 can be made in the form of tubular element 7 with covers 8, each opposite end of the tubular element being provided by a group of electrodes 4 (not shown) located on a cylinder generatrix line. Covers 8 can be of semi-spheroid, cupola, or other form.

The capsule 1 can be made in the form of two interconnected caps 9, each being provided by a group of electrodes 4. Caps 9 can be of conic or other form.

Unit 5 for testing parameters of external medium can be made in the form of resistance at electrodes 4 measuring block and contain voltage divider 10 connected with power supply 3 and having outputs connected with the pair of differently polarized electrodes 4, and comparator 11. The inverting input of comparator 11 is connected through resistor 12 with power supply 3, and the non-inverting input - with the output of voltage divider 10.

The output of comparator 11 is the control input of pulses driver 6.

Pulses driver 6 can contain three-stable linear keys 13 providing for feeding of each electrode 4 by the signal levels of "+" or "-" from power supply 3 as well as switching them off from the power supply, pulses in series distributor 14 consisting of counter 15 and coder 16 and providing for consequential connection of keys' voltage inputs to the output of counter and blocking of unused keys, controlled frequency divider 17 providing for formation of a pulsing sequence from

necessary number of pulses in a series with repetition frequency of series close to frequency of the natural peristalsis wave, and monitoring synchronizer 18 producing frequency which is necessary for formation of the required duration of stimulating pulses (6-10 ms.).

The electrical stimulant works as follows (this is an example for the multi-electrodes form as the form more complicated for the understanding of its functioning).

The electrical stimulant is entered, for example, into the alimentary tract of a patient per oral, i.e. by swallowing.

In the initial mode (before the entering into the alimentary tract) the electrical stimulant is in the non-working position, at which the voltage from voltage divider 10 blocks pulses driver 6 through unit 5 for testing parameters of external medium.

The voltage from voltage divider 10 drops after the entering into the alimentary tract of capsule 1 due to the impact of external medium (saliva, gastric juice and so on) and unit 5 for testing parameters of external medium comes to the condition permitting to start on pulses driver 6.

The series of pulses, which parameters are determined by the external medium pH factor, comes from pulses driver 6 to electrodes 4. Thus pulses driver 6 executes such commutation of electrodes 4 for each series of pulses, which commutation provides for activating, for example, simultaneously, pairs of differently polarized electrodes from the same group as well as from the electrodes from the opposite groups. Such activation of the pairs of electrodes with mutually orthogonal electrical field strength directions provides for simultaneous or consecutive excitation the longitudinal as well as circular layers of muscular tissue irrespective of capsule orientation in any part of the alimentary tract, that increases essentially electrical stimulating efficiency. The electrical

impact on the muscular tissue causes response in the form of the stable peristalsis wave which transports the electrical stimulant and contents, for example, of the alimentary tract, to its distal part which is influenced by the next series of pulses and the process is repeated until the capsule will come out by the natural way.

CLAIMS:

1. An electrical stimulant of the alimentary tract containing a capsule with two electrodes, which are provided on the outer surface of the capsule, and the power supply located inside, characterized by that a unit for testing parameters of external medium and a pulses driver, which are consecutively connected, are additionally located in the capsule, and n electrodes, where n = 0, 1, 2, ..., and it is defined by a degree of healing effect for some or other disease and technological possibility of the electrodes manufacture, are provided on the external surface of the capsule, the electrodes being connected with outputs of the pulses driver and two electrodes of the total number of the electrodes are connected with inputs of the unit for testing of parameters of external medium.

2. The electrical stimulant of the alimentary tract according to the claim 1, characterized by that the capsule is made in the form of a tubular element with covers, each opposite end of the tubular element being provided by a group of electrodes located on the cylinder generatrix line.

3. The electrical stimulant of the alimentary tract according to the claim 1, characterized by that the capsule is made in the form of two interconnected caps, each being provided by a group of electrodes located on the generatrix line of the cap.

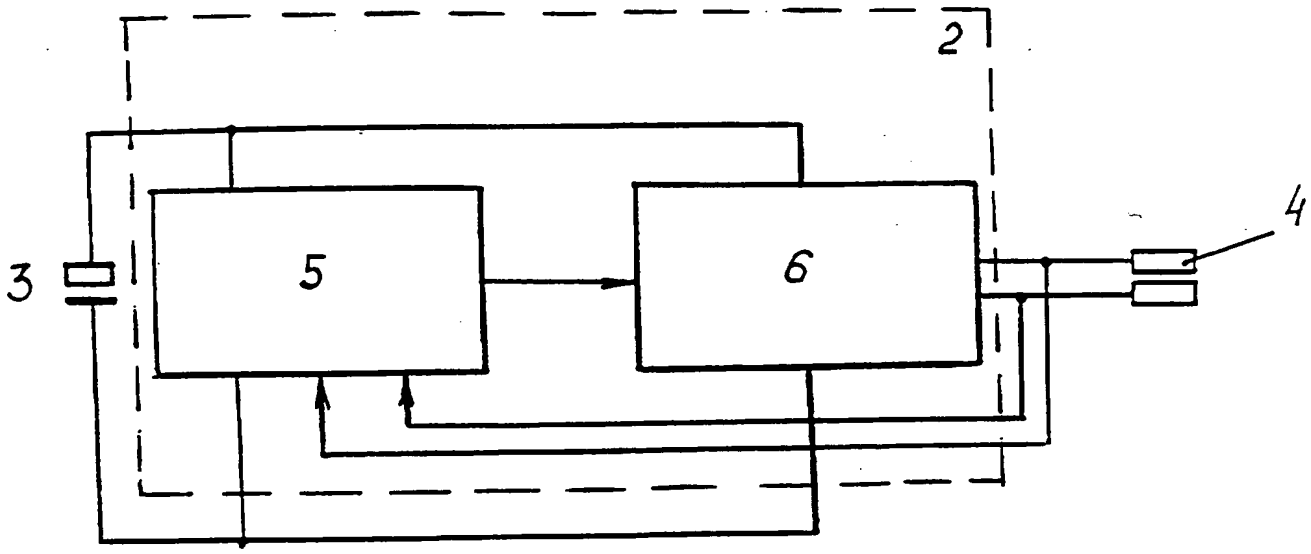


Fig.1

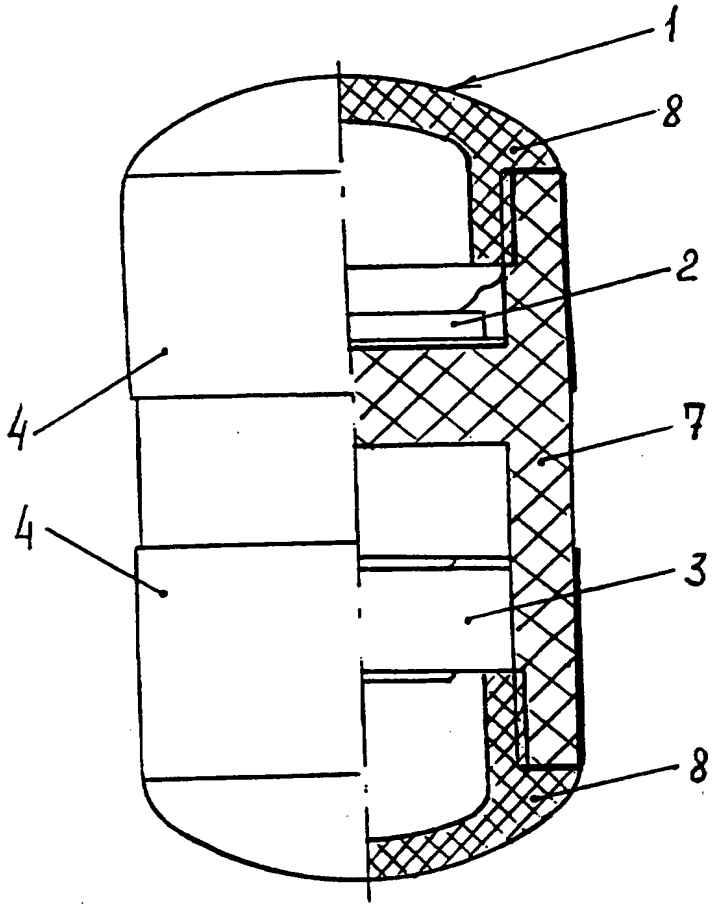


Fig.2

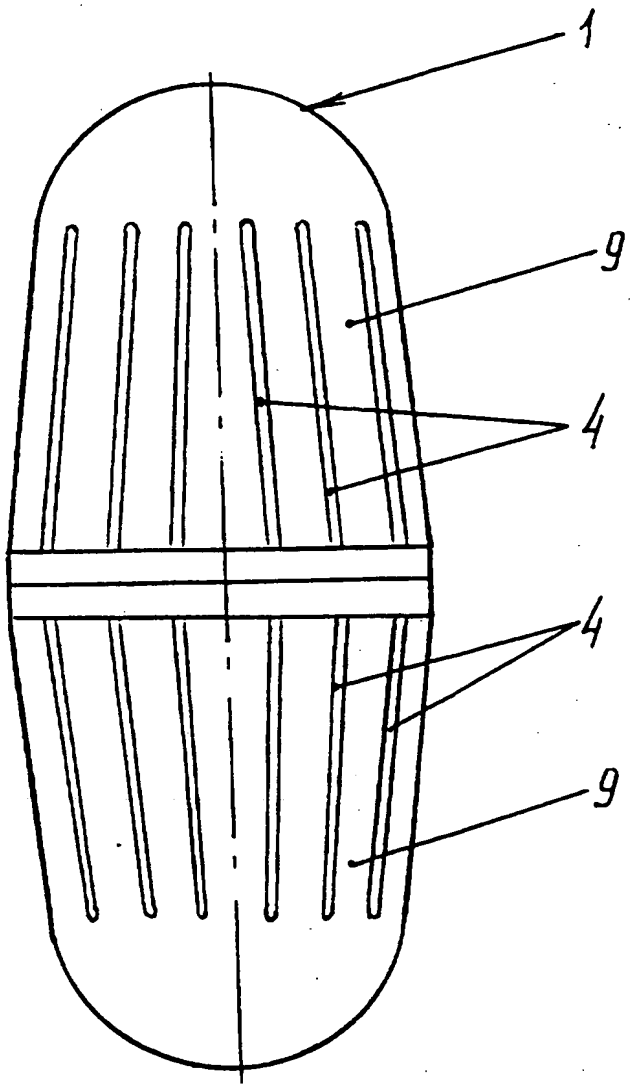


Fig.3

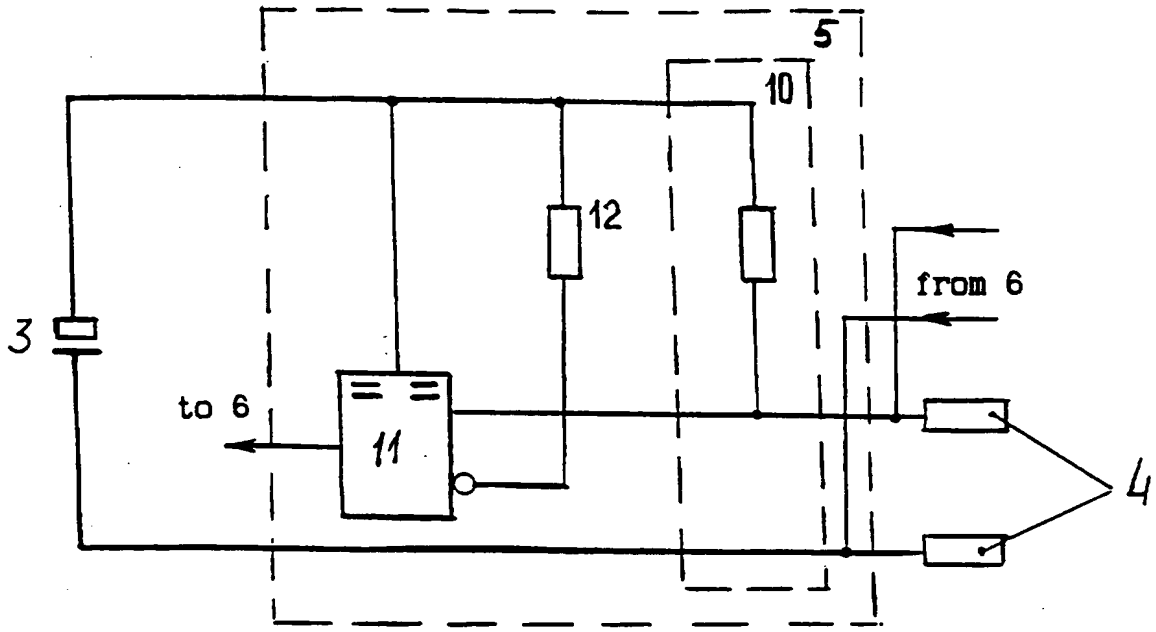


Fig.4

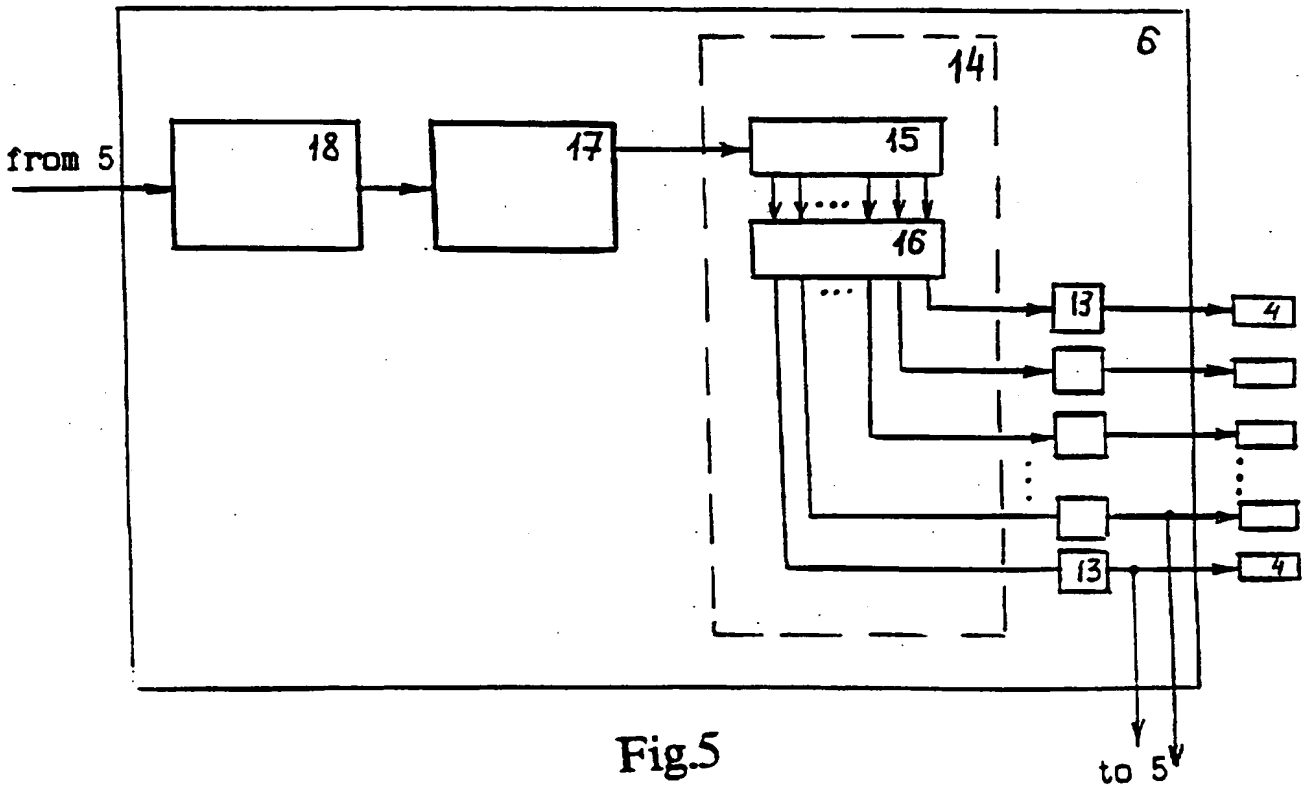


Fig.5

INTERNATIONAL SEARCH REPORT

Int. onal Application No
PCT/RU 96/00311

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61N1/36

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Mimmum documentation searched (classification system followed by classification symbols)
IPC 6 A61N A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 88 00449 A (C.B.BIOELETTRONICA) 28 January 1988 see the whole document ---	1
A	WO 94 01172 A (DOUGLAS) 20 January 1994 see the whole document ---	1
A	EP 0 193 251 A (CORNING GLASS WORKS) 3 September 1986 see abstract ---	1
A	US 3 719 183 A (SCHWARTZ) 6 March 1973 see the whole document ---	1
A	US 5 358 514 A (SCHULMAN) 25 October 1994 see the whole document --- -/--	1

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

1

Date of the actual completion of the international search	Date of mailing of the international search report
11 April 1997	18. 04. 97

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Taccoen, J-F

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Int. onal Application No
PCT/RU 96/00311

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 209 238 A (SUNDHAR) 11 May 1993 see the whole document -----	1

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int onal Application No
PCT/RU 96/00311

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 8800449 A	28-01-88	DE 3779895 A	23-07-92
		EP 0274499 A	20-07-88
WO 9401172 A	20-01-94	US 5292344 A	08-03-94
		AU 662076 B	17-08-95
		AU 4666993 A	31-01-94
		CA 2138792 A	20-01-94
		EP 0656796 A	14-06-95
		JP 7508662 T	28-09-95
EP 0193251 A	03-09-86	GB 2096825 A	20-10-82
		EP 0063455 A	27-10-82
		US 4502938 A	05-03-85
		US 4567006 A	28-01-86
US 3719183 A	06-03-73	NONE	
US 5358514 A	25-10-94	US 5405367 A	11-04-95
		US 5193540 A	16-03-93
US 5209238 A	11-05-93	WO 9423653 A	27-10-94
		AU 4284493 A	08-11-94